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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,143	07/11/2003	Paz Einat	2094/6773-A/JPW/FHB	8204

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EXAMINER	
REDDIG, PETER J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,143	EINAT ET AL.	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 12 and 13, drawn to an antisense oligonucleotide capable of inhibiting the expression of the IDH polypeptide, classified in class 536, subclass 23.1.

II. Claims 1-11, drawn to a method for treatment of an apoptosis related disease in a subject comprising administering to said subject a therapeutically effective amount of an inhibitor of the IDH polypeptide, classified in class 424, subclass 130.1.

III. Claims 14, 16, and 18, drawn to a process for determining the level of the IDH polypeptide in a subject to determine the potential and actual response to chemotherapeutic treatment and the diagnosis of cancer, classified in class 435, subclass 7.6.

IV. Claims 15,17, and 19, drawn to a process for determining the level of the IDH mRNA in a subject to determine the potential and actual response to chemotherapeutic treatment and the diagnosis of cancer, classified in class 435, subclass 6.

V. Claims 20-22 drawn to process for obtaining a compound which modulates apoptosis classified in class 435, subclass 375.

VI. Claims 23 and 24, drawn to a process for obtaining a compound, which modulates apoptosis through the human IDH polypeptide, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

The nucleotide product of Group I and the method of Group II are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant, case the nucleotide product as claimed in Group I can be used in a materially different process such as nucleic acid hybridization assays.

Furthermore, searching all of the claims of Groups I and II would invoke a burdensome search because the inventions have been classified separately. Thus, each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. This would necessitate different searches in the patent and or non-patent literature and the consideration of different patentability issues.

The nucleotide product Group I and the methods of Groups III-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the nucleotide product nucleotide product is not disclosed as capable of use in the methods described in Groups III-VI. Additionally, the steps for executing the methods in Groups III-VI do not require the nucleotide product of Group I.

Furthermore, searching all of the claims Groups I and III-VI would invoke a burdensome search because the inventions have been classified separately. Thus, each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search.

This would necessitate different searches in the patent and or non-patent literature and the consideration of different patentability issues.

The method inventions of Group II, III, IV, V and VI are materially distinct methods, which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. The methods are related in that they employ IDH (mRNA or polypeptide) either as target for inhibition (Group II) or as a biomarker for diagnosis, treatment, and the identification of modulators of apoptosis (Groups III-VI).

The method of Group II is distinct from Groups III-VI in that it is drawn to a method for treatment of apoptosis related diseases through the inhibition of the IDH polypeptide. For example, it utilizes the distinct step of administering an IDH inhibitor, such as an antibody, to a subject. Groups III-VI do not employ this step in their methods and thus are distinct from Group II. Furthermore, because Group II and Groups III-VI have been classified separately, thus having attained recognition in the art as separate subject matter for inventive effort, searching all of the claims would invoke a burdensome search.

The method of Group III drawn to a process for determining the level of the IDH polypeptide in a subject to determine the potential and actual response to chemotherapeutic treatment and the diagnosis of cancer is distinct from the methods of Groups II, IV, V, and VI. The method of Group III employs the distinct step of determining the level of the IDH polypeptide, which is not used in the methods of Groups II, IV, V, and VI. Furthermore, searching all of the claims these distinct Groups would invoke a burdensome search because the inventions have been classified separately. Thus, each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. This would

necessitate different searches in the patent and or non-patent literature and the consideration of different patentability issues.

The method of Group IV drawn to a process for determining the level of the IDH mRNA in a subject to determine the potential and actual response to chemotherapeutic treatment and the diagnosis of cancer is distinct from the methods of Groups II, III, V, and VI. The method of Group III employs the distinct step of determining the level of the IDH mRNA, which is not used in the methods of Groups II, III, V, and VI. Furthermore, because Group IV and Groups II, III, V, and VI have been classified separately, thus having attained recognition in the art as separate subject matter for inventive effort, searching all of the claims would invoke a burdensome search.

The method of Group V drawn to process for obtaining a compound which modulates apoptosis is distinct from the methods of Groups II, III, IV, and VI. The method of Group V employs the distinct steps of providing cells that express the human IDH polypeptide, contacting the cells with a compound that modulates apoptosis, and determining the ability of said compound to modulate apoptosis. These steps are not employed in Groups II, III, IV, and VI. Furthermore, searching all of the claims these distinct Groups would invoke a burdensome search because the inventions have been classified separately. Thus, each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. This would necessitate different searches in the patent and or non-patent literature and the consideration of different patentability issues.

The method of Group VI drawn to process for obtaining a compound which modulates apoptosis through the human IDH polypeptide is distinct from the methods of Groups II, III, IV,

and V. The method of Group VI employs the distinct steps of contacting the IDH polypeptide with a compound that modulates apoptosis and measuring the activity of the IDH polypeptide. These steps are not employed in Groups II, III, IV, and V. Furthermore, because Group VI and Groups II, III, IV, and V have been classified separately, thus having attained recognition in the art as separate subject matter for inventive effort, searching all of the claims would invoke a burdensome search.

Species Election for Group II

Claims 3-5 and 8-10 are generic to the following disclosed patentably distinct species of "IDH inhibitors":

1) antibody (Claims 3 and 8)

2) 2-(4-bromo-2, 3-dioxobutylthio)-1 (Claims 4 and 9)

3) N6-ethenoadenosine 2', 5'-bisphosphate (Claims 4 and 9)

4) NADP oxoglutatrate (Claims 4 and 9)

5) o-(carboxymethyl) oxalohydroxamate (Claims 4 and 9)

6) oxalylglycine (Claims 4 and 9)

7) 3-bromo-2-ketoglutarate (Claims 4 and 9)

8) beta-mercapto-alpha-ketoglutarate (Claims 4 and 9)

9) beta-methylmercapto-alpha-ketoglutarate (Claims 4 and 9)

10) beta-methylmercapto-alpha-hydroxyglutarate. (Claims 4 and 9)

11) adriamycin (Claims 4 and 9)

12) alpha-methylisocitrate (Claims 4 and 9)

13) AS fragment comprising consecutive nucleotides having the sequence set forth in SEQ ID NO: 5 (Claims 5 and 10)

The products of the above species represent separate and distinct molecules with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Peter J. Reddig, Ph.D.
Examiner
Art Unit 1642

PJR

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER